

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE March 24, 2010

FROM Bhanu Kannan, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch, HFM-664

TO Thomas Finn, Ph.D., HFM-715
Chair, BLA Licensing Committee

SUBJECT ***Summary of Bioresearch Monitoring Inspections***
SPONSOR: Dendreon Coporation
PRODUCT: Sipuleucel-T (APC8015-autologous antigen presenting
cells loaded with prostate antigen PA2024)
BLA: STN 125197/0/33

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5 Pages withheld per the privacy act

